EXPERT'S DECLARATION UNDER 37 C.F.R. § 1.132

I, Dr. Ivo Pischel, Ph.D., declare as follows:

1. I am a citizen of Germany and reside at Lacher Weg 1, D-53547 Rossbach, Germany. I graduated from the University of Bonn with a degree in Medicine in 1992 and received a Ph.D. from the University of Bonn in 1995. I have had over nine years of R&D experience within the nutraceutical industry, working for SKW Trostberg AG (now: Degussa AG) and its subsidiary Degussa BioActives GmbH. Since March, 2002, I have been the Executive Vice President of R&D Dietary Supplements of Finzelberg GmbH & Co. KG, Germany.

2. I have read and am thoroughly familiar with the contents of the above-identified patent application as well as of the prior art references cited in the application. I have read and I understand amended claim 13.

3. As an expert in the field of muscle physiology, I can agree to the results found in trials that when healthy skeletal muscle of an animal or human is treated with creatine in unit dosage form with at least two or more daily doses of about 5 g of creatine, in which treatment is begun when the animal or human is confined temporarily to bed rest, due to some other condition that necessitates such bed rest for several weeks, the incidence of muscle disuse syndrome in the healthy skeletal muscle is significantly reduced or avoided completely when compared to non-treated animals or humans.

4. Furthermore, upon commencement of a physical rehabilitation program, after the temporary immobilization has ended, continuing creatine administration continuing at a lower dose of about 5 g daily results in more rapid skeletal muscle rehabilitation than skeletal muscle that has not been treated previously with creatine according to the temporary immobilization treatment protocol. Thus, the treatment protocol of the present invention allows for enhanced rehabilitation lasting no longer than about one to two weeks.

5. I can concur with the investigated effects of creatine administration on skeletal muscle in individuals according to the treatment protocol of the present invention, and have found that the skeletal musculature of the treated individuals had significantly greater body mass, significantly greater muscle cross-sectional area, significantly greater muscle power output, significantly greater maximal isometric knee-extension torque, and significantly decreased muscle relaxation time, when compared to non-treated control individuals.

6. Furthermore, I can assert the investigated effects of administering creatine according to the treatment protocol of the present invention on muscle glycogen and glucose tolerance and have found that after several weeks of rehabilitation training, muscle glycogen concentration was significantly higher when compared to non-treated control individuals.

7. It is my understanding that WO 98/00148 discloses the administration of creatine for the therapeutic use of improving muscle mass, function, stamina, shortening the recovery after physical strain after post-operative muscle atrophy, treatment of heart complaints, different types of myopathy and cachectic states. I further understand that Pischel et al. teach a method of administering creatine ascorbates for enhancing muscular development and as a prophylactic against and treatment for ischemia and muscular atrophy, but does not specify a dosage wherein the amount of creatine is decreased upon treatment, although Howard et al. teach administering 20-30 grams creatine per day for several days and thereafter decreasing the dosage to no more than 2 to 3 grams per day. Additionally, I understand that XP-00210314 (Wyss) teaches two creatine supplement approaches: one continuous and the other intermittent at high doses, but does not specify the creatine dose. Finally, I understand that WO 98/00148 discloses drug preparations containing creatine for treatment of heart complaints, respiratory deficiencies, emphysema, after operations, fibromyalgia, myopathy, cathectic states, or generally to eliminate states of deficiency, such as nutritional deficiencies.

8. It is my opinion that no one skilled in the art would have understood the claimed invention from the disclosures contained in the above-cited prior art because none of the disclosures teaches or suggests administering creatine to treat healthy skeletal muscle that commences at the onset of a temporary immobilization period brought on by forced bed rest that lasts several weeks necessitated by another condition, and that continues at a lower dosage during a physical rehabilitation program that lasts no more than ten days because of the enhanced rehabilitation of the skeletal musculature. Indeed, all of the disclosures contained in the above-cited prior art teach the administration of creatine generally for a specific muscular-related disease or disorder, such as myopathy, muscle atrophy, heart complaints, cathectic states, ischemia, respiratory deficiencies, nutritional deficiencies, emphysema or fibromyalgia. Additionally, none of the disclosures teach or suggest the temporal parameters of administration, i.e., creatine administration beginning at the commencement of forced bed rest that lasts for several weeks and continuing during the rehabilitation period for no longer than ten days, which is a key feature of the present invention responsible for the new and

unexpected results heretofore described. Furthermore, the proactive treatment of healthy skeletal muscle would not be obvious in any way from the above-cited prior art teachings of reactively treating compromised muscle.

9. I declare further that all statements made herein of my own knowledge are true and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application and any patent issuing thereon.

Dr. Ivo Pischel, Ph.D.

Jan 10, 2005
Date